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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/173,864	10/16/1998	ROBERT D. IVARIE	24011-0002	4740

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EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/173,864

Applicant(s)

IVARIE ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-69 is/are allowed.
- 6) ☒ Claim(s) 60-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 07/01/02 has been acknowledged.
The SEQ listing filed on 01/2/03 has also been acknowledged.

*Claims 19, 27, 35, 43-45, 53-55 and 57-59 are canceled.
Claims 60-69 are newly filed claims.
Claims 60-69 are pending and are examined in this office action.*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

► *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing of all claims** in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.*

Applicant's arguments filed on 07/01/02 (page 4) have been fully considered but are moot in view of the new ground(s) of rejection below as necessitated by the recent amendments.

Claim Rejections - 35 USC § 103

Claims 60, 62-63 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thoraval et al (Trans. Res. 4:369-376, 1995, ref of record) in view of Bosselman et al (US 5162215, 1992, ref. of record).

The invention as claimed is drawn to a transgenic chicken and method of making the same, wherein the transgenic chicken encodes an exogenous interferon- α or erythropoietin in the genetic material of its germ line tissue. The invention of instant claims does not require that the chicken produce exogenous interferon- α or erythropoietin protein in an egg obtained from the transgenic chicken as claimed.

Thoraval et al teaches the germline transmission of exogenous genes in chickens using helper-free ecotropic avian leukosis virus (ALV) based vector (see abstract, page 371, col.2, table-1 and par.1). The cited art teaches an ALV vector encoding neomycin or lacZ marker genes. The cited art further teaches introduction of the viral vector into embryonic cells contained in a freshly laid eggs (page 370, col.2). The cited art further teaches the mating of transgene positive birds to produce transgenic chickens (col.371, para.2). In addition the cited art teaches the analysis of G1 progeny from G0 positives cocks (page 372, table-2).

Bosselman et al teaches the micro-injection of a replication-defective REV-derived retroviral vector inside the egg around the blastoderm. After the injection the eggs are sealed and incubated to form chicks (col/8 line 45-66). The cited art further teaches the transfer of nucleic acid sequences encoding desirable protein products like human serum albumin, alpha1-antitrypsin, blood clotting proteins (factor VIII) and hematopoietic growth factors (EPO, G-CSF, LGF) to make transgenic chickens (col.6 line 8-17). The cited art teaches a method for obtaining a transgenic chicken whose germ cells contain a nucleic acid sequence of a replication-defective REV-derived vector in the absence of an exogenous replication-competent helper retrovirus comprising: (a) obtaining a laid chicken egg which is not more than two days old and which contains an embryo; (b) making an opening in the egg to expose a blastoderm; (c) microinjecting through the opening a solution containing the replication-defective REV-derived vector into an area around and in close proximity to the blastoderm; (d) sealing the opening after microinjection; (e) incubating the sealed microinjected egg at 37.degree.C to allow development of the embryo; (f) maintaining the incubation until the chicken is viably hatched from the egg; (g) breeding said chicken to produce progeny chickens; and (h) identifying progeny chickens not productively infected by the helper retrovirus and carrying the nucleic acid sequence. (see col.17-18, especially claim 11).

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Thus it would have been obvious to one ordinary skill in the art at the time of invention to modify the teaching of Thoraval by substituting the marker genes by EPO gene as taught by Bosselman. One would have been motivated to do so because EPO is a gene of interest, since it regulate erythropiosis in animals. Thus the method for producing a transgenic chicken as claimed is prima facie obvious in view of cited art or record.

Claims 61 and 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thoraval et al (Trans. Res. 4:369-376, 1995, ref of record) as applied to claims 60, 62-63 and 65 above, and further in view of Petite et al (US 5784992, 1998).

Petite et al (US 5784992, 1998) teaches a method of injecting an avian embryo in an egg with DNA constructs encoding physiologically active polypeptides, wherein the polypeptide is selected from an interferon, interleukin-2, insulin like growth factors and thyroid hormone (abstract; col.3, line 5-18; col.4, line 43-51; col.5, line 32-46).

Thus it would have been obvious to one ordinary skill in the art at the time of invention to modify the teaching of Thoraval by substituting the marker gene by an interferon gene as taught by Petite. One would have been motivated to do so because interferon is a gene of interest, since it protect animals from viral and other infections. Thus the method for producing a transgenic chicken as claimed is prima facie obvious in view of cited art or record.

Conclusion

Claims 60-65 are rejected because the product and the method as claimed is obvious in view of prior art of record.

Claims 66-69 are free of prior art of record. Even though the prior art teaches transgenic chickens and method of making the transgenic chicken that encodes exogenous exogenous interferon- α or erythropoietin protein in the germ line tissue, the method of producing an exogenous exogenous interferon- α or erythropoietin protein in an egg of a transgenic chicken is an unexpected result. Therefore a transgenic chicken that produces exogenous interferon- α or erythropoietin in its egg is also found free of prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner



JEFFREY FREDMAN
PRIMARY EXAMINER